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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903

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CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
12TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/26/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,544

Applicant(s)

COSTANZO ET AL.

Examiner

Simon J. Oh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6, 7, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

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In the present instance, Claim 1 recites the broad recitation “less than 1 %”, and the claim also recites “and preferably less than 0.5 %”, which is the narrower statement of the range/limitation.

Claim 2 recites the broad recitation “greater than 5 mm”, and the claim also recites “and preferably greater than 17 mm”, which is the narrower statement of the range/limitation.

Claim 3 recites the broad recitation “at least 35°C”, and the claim also recites “and preferably higher than 50°C”, which is the narrower statement of the range/limitation.

Claim 6 recites the broad recitation “in the range 0.2 to 10 parts per 1000”, and the claim also recites “and is preferably in the range 3 to 6 parts per 1000”, which is the narrower statement of the range/limitation.

Claim 7 recites the broad recitation “preferably less than 30 microns”, and the claim also recites “and more preferably still, less than 10 microns”, which is the narrower statement of the range/limitation.

Claim 12 recites the broad recitation “the range 3 kN to 50 kN”, and the claim also recites “preferably in the range 4 kN to 40 kN, or more preferably still, in the range of 5 kN to 25 kN”, which is the narrower statement of the range/limitation.

Claims 1 and 11 both contain the phrase “at least a major amount”, rendering these Claims indefinite. It is unclear what is precisely meant by this limitation and what sort of condition will satisfy this limitation. How much is enough? At least 35%? At least 51%? At least 75%?

Claim 1 is rejected for containing the reference to criteria found in the French Pharmacopoeia. All claims must be complete in and of themselves.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu *et al.*
(U.S. Patent No. 6,465,009 B1)

The Liu *et al.* patent teaches pharmaceutical dosage forms for a rapidly disintegrating buccal tablet (See Column 1, Line 49 to Column 2, Line 3). The tablets dissolve in about 1 to about 40 seconds in an aqueous solution, which is typically saliva (See Column 2, Lines 45-51). Processes for making this tablet are disclosed (See Column 2, Line 52 to Column 3, Line 55). The tablets can comprise saccharides of various moldabilities, including mannitol, lactose, glucose, sucrose, lactitol, maltose, maltitol, and sorbitol (See Column 2, Lines 27-39). A lubricant, such as magnesium stearate, can be included in the tablets in amounts ranging from 0.1% to 2.0% by weight of the tablet (See Column 7, Lines 55-63). A disintegrant may be included as well, such as croscarmellose sodium and sodium starch glycolate (See Column 7, Line 64 to Column 8, Line 2). Other additives may also be included as well, such as colorants and sweeteners (See Column 8, Lines 29-45). The use of polyvinylpyrrolidone as a binder for the purpose of reducing the friability of a tablet is disclosed, and examples are given that illustrate how friability can be manipulated to below 1.0% (See Column 7, Lines 21-34; and Examples). In particular, Example 7 shows one set of tablets that exhibit a friability of about

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2.7±2.2%, which the examiner will interpret to mean a range from about 0.5% to about 4.9%. In Example 8, Tablet B exhibits a friability of 0.8 ±0.5%. The limitations in Claim 1 regarding its ability to be packaged is interpreted to be directed toward a future intended use of the tablet, and is therefore not given any patentable weight. Claim 10 is directed toward a future intended use of the claimed tablet, and this limitation of intended use is not given patentable weight by the examiner. Therefore, the examiner considers the tablet of Claim 10 to be anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.*

The relevant portions of Liu *et al.* are given in the above rejection of Claims 1, 3-6, 8-11 under 35 U.S.C. 102(e).

The limitations of Claims 2, 7, and 12 are not considered to be critical to the function of the instantly claimed invention. Absent a showing of criticality or of results that would be unexpected by one of ordinary skill in the art at the time the invention was made, these claims are not considered to be patentable above the prior art. The examiner also points out in Liu *et al.*, Column 4, Lines 35-48, there is a description of the moldability of various saccharides,

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which the examiner will interpret to read on various process conditions, particularly die diameters and compression pressures.

Thus, the instantly claimed invention is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sj
March 19, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600